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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,300	05/11/2001	Gregory Ford	STAN177	7800

7590

06/04/2002

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EXAMINER

HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/04/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,300

Applicant(s)

FORD ET AL.

Examiner

"Neon" Phuong Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.

- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Fax cover sheet*.

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.
2. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
3. Claims 1-19 are pending.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10, drawn to an isolated **nucleic acid molecule** encoding a GRAIL protein of SEQ ID NO: 5, or a fragment thereof, an isolated nucleic acid that hybridizes under stringent conditions to nucleic acid molecule encoding a GRAIL protein of SEQ ID NO: 5, an expression cassette comprising a transcriptional initiation region functional in an expression host comprising said nucleic acid molecule, a cell comprising said expression cassette, a method for producing said Grail protein, classified in Class 536, subclass 23.5, Class 435, subclass 69.1, Class 435, subclass 252.3, subclass 252.33.
 - II. Claims 1-10, drawn to an isolated **nucleic acid molecule** encoding a GRAIL protein of SEQ ID NO: 7, or a fragment thereof, an isolated nucleic acid that hybridizes under stringent conditions to nucleic acid molecule encoding a GRAIL protein of SEQ ID NO: 5, an expression cassette comprising a transcriptional initiation region functional in an

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expression host comprising said nucleic acid molecule, a cell comprising said expression cassette, a method for producing said Grail protein, classified in Class 536, subclass 23.5, Class 435, subclass 69.1, Class 435, subclass 252.3, subclass 252.33.

- III. Claims 11-13, drawn to a purified **polypeptide composition** comprising at least 50% by weight of the GRAIL protein wherein said polypeptide comprises the amino acid sequence encoded by SEQ ID NO: 5 or a polypeptide fragment of at least 12 amino acids and comprising a sequence within SEQ ID NO: 6, classified in Class 424, subclass 185.1.
- IV. Claims 11-13, drawn to a purified **polypeptide composition** comprising at least 50% by weight of the GRAIL protein wherein said polypeptide comprises the amino acid sequence encoded by SEQ ID NO: 7 or a polypeptide fragment of at least 12 amino acids and comprising a sequence within SEQ ID NO: 8, classified in Class 424, subclass 185.1.
- V. Claim 14 drawn to an **antibody** specific for a purified polypeptide composition comprising at least 50% by weight of the GRAIL protein wherein said polypeptide comprises the amino acid sequence encoded by **SEQ ID NO: 5**, classified in Class 530, subclass 387.1.
- VI. Claim 14 drawn to an **antibody** specific for a purified polypeptide composition comprising at least 50% by weight of the GRAIL protein wherein said polypeptide comprises the amino acid sequence encoded by **SEQ ID NO: 7**, classified in Class 530, subclass 387.1.
- VII. Claim 15 drawn to a **method of screening** for biologically active agents that modulate GRAIL function using a GRAIL **polypeptide** or fusion derived therefrom, and determining the effect of said agent on GRAIL function, classified in Class 435, subclass 7.8.

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- VIII. Claim 15 drawn to a **method of screening** for biologically active agents that modulate GRAIL function using a cell comprising a **nucleic acid** encoding a GRAIL polypeptide, and determining the effect of said agent on GRAIL function, classified in Class 435, subclass 6.
- IX. Claim 15 drawn to a **method of screening** for biologically active agents that modulate GRAIL function using a **non-human transgenic animal** model for GRAIL gene function comprising an exogenous and stably transmitted GRAIL gene sequence, and determining the effect of said agent on GRAIL function, classified in Class 800, subclass 2.
- X. Claim 15 drawn to a **method of screening** for biologically active agents that modulate GRAIL function using a **non-human transgenic animal** comprising a **knockout** of an GRAIL gene, and determining the effect of said agent on GRAIL function, classified in Class 800, subclass 2.
- XI. Claim 15 drawn to a **method of screening** for biologically active agents that modulate GRAIL function using a **non-human transgenic animal** model for GRAIL gene function comprising an **GRAIL promoter sequence operably linked to a reporter gene**, and determining the effect of said agent on GRAIL function, classified in Class 800, subclass 2.
- XII. Claim 16, drawn to a **method of characterizing the expression of sequences** associated with anergy induction or maintenance in T cells using murine sequences set forth in SEQ ID NO: 1-5, classified in Class 435, subclass 91.42.
- XIII. Claim 16, drawn to a **method of characterizing the expression of sequence** associated with anergy induction or maintenance in T cells using a human sequence set forth in SEQ ID NO: 7, classified in Class 435, subclass 91.42.

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The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the products as claimed such as nucleic acid and polypeptide from different species and antibody differ with respect to structure and physiochemical properties. Therefore, they are patentably distinct.

Inventions of Groups VII-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of screening and characterizing the expression using distinct products (polypeptide, nucleic acid, transgenic or knockout non-human animal) which differ with their respect to their process steps and endpoints. Therefore, they are patentably distinct.

Inventions of Groups (I-VI) and Groups (VII-XIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as claimed can be used in materially different process such as treating immune diseases. Therefore, they are patentably distinct.

5. Because these inventions are distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper.
6. Due to the complexity of the claimed invention an oral restriction was not made.
7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

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8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
10. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

June 3, 2002


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600